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**WO 01/01950 A1**

(54) Title: **PRE-FORMED GEL SHEET**

(57) Abstract: A pre-formed, sheet device comprising; (a) less than 10 % of a polysaccharide mixture consisting of; (i) a red seaweed polysaccharide; (ii) a mannose containing polysaccharide selected from a galactomannan, glucomannan, and derivatives or mixtures thereof and; (iii) a fermentation polysaccharide, or derivatives thereof; and (b) from about 30 % to about 99.5 % of water; wherein the device comprises less than 10 % total polysaccharide. The pre-formed, sheet devices of the invention are suitable for topical application and display desirable amounts of syneresis and/or improved mechanical properties such as strength or flexibility, as well as excellent moisturisation, hydration and cooling benefits. Further, the devices of the present invention are easy to handle, unobtrusive and conform to the contours of a target surface when applied.

Further, some patches or devices require formation *in-situ* on the skin and are therefore messy to apply. For example, US-A-4,291,025 relates to a thermally reversible agar gel topical dressing comprising 5 to 12% agar, 20 to 75% diethylene glycol and water to 100 wt % and methods for preparing said dressing. The compositions may additionally comprise gel strengthening agents and special purpose ingredients (e.g. vitamins, antibiotics). According to one aspect of the invention of US-A-4,291,025, solid, high strength, yieldable agar gels are prepared and then subdivided into smaller pellets or pieces. According to a further aspect, the agar gel is then converted into a sol upon heating wherein the sol is applied to the target skin and cooled *in-situ* to form a removable gel form.

Flexibility and strength are important features of a gelled device. WO97/17944 discloses cosmetic formulations made up of a gel material consisting of a balanced mixture of polysaccharides containing a soluble alginate (0.1-5%), agar (0.01-0.5%), pectin (0.01-0.5%), xanthan gum (0.05-1%) with the balance consisting of water. The gel material is optionally enriched with water-soluble or water-dispersible active ingredients. The gel material may be processed to form a structured gel which is disclosed as being easy to handle and well adapted to the skin surface.

US-A-4,318,746 relates to a gel comprising at least 0.5% of a first polymer that disperses, dissolves or hydrates in hot water and that forms, or can be made to form, a rigid gel on cooling, at least 2% of a second polymer that is insoluble in hot water and that dissolves or hydrates on cooling and is compatible with the first polymer, and water. The document describes the gel as being firm, cohesive and adhesive and useful for example, as an electrode or for the topical administration of drugs. The document outlines that one of the advantages of the gel is that it is relatively rigid and adhesive at temperatures below 60-65°C.

WO90/14110 discloses pharmaceutical preparations which may take the form of a self-supporting slab, pad or wafer of a desired size, shape and thickness comprising a water insoluble alginate and suspending agents such as xanthan gum alone, or xanthan gum in combination with locust bean gum. Gellan gum is also disclosed as a further useful suspending agent. The suspending agents in the preparations may also act as gel forming agents. The preparations optionally comprise anti-inflammatory agents, or the antiseptic agent, iodine. The slab or wafer forms of a preparation may be applied onto a plastic backing to form an integral surgical dressing, with the gel either exposed or covered with a gauze.

All gels undergo syneresis to some degree. That is, upon standing, the gel contracts with the exudation of liquid. Syneresis provides a mechanism for delivery of a benefit agent to a target area. The liquid layer of exudate formed on the surface of the gelled medium is readily available for diffusion facilitating a short wear time of the device. A moderate amount of syneresis has been found by the present inventors as a highly desirable property of a device comprising a gel, as the liquid exuded onto the surface of the gelled device facilitates its adhesion to a target surface thus obviating the need for either an additional adhesive overlaying the gelled form or an adhesive coated substrate. By comparison, if a gelled device exhibits too little syneresis, the device, although wetting an area, is not likely to provide good adhesion to the target area, whilst an excessive amount of syneresis results in an ineffective and unattractive product.

EP-A-161 681 discloses gel plates comprising a polysaccharide and an aqueous solution of a polyhydric alcohol. Preferred polysaccharides for the gel plates are a blend of carrageenan and a galactomannan, or carrageenan alone. The compositions optionally comprise medical components such as skin stimulants, antiphlogistics, analgesics and antibiotics. The gel plates are disclosed as being transparent or inconspicuous, having a refreshing feeling and good adhesion, as well as being sufficiently elastic, stretchable and strong. The present inventors have found however, that the gel plates described by EP-A-161681 do not display a desirable amount of syneresis.

JP-B2-276 1936 discloses aqueous sheet-like packs comprising xanthan gum and locust bean gum in combination with a water-soluble solvent. The sheet-like packs of the invention are disclosed as having excellent shape retention properties at high temperature, providing a moist feel and having a high skin moisturising effect. The examples disclose that the packs may further comprise 0.1% of a skin beautifying component.

JP-A-54 92618 discloses a wet compress comprising an aqueous calcium ion cross-linked alginate gel as a base, substances having an antiphlogistic and analgesic action and water. Example 5 discloses a wet compress comprising a mixture of locust bean gum, konjac powder, a 3% sodium alginate solution, a calcium monohydrate phosphate source and a styrene-butadiene copolymer latex. The document teaches that the addition of water soluble polymers increases the shape retaining power of a compress and a highly elastic gel is obtained by adding locust bean gum and konjac mannan, or carrageenan alone. However, the addition of water soluble polymers such as konjac and locust bean gum, amongst others, to the wet compress is taught as impeding the release of water. Further, the base containing gels of the wet compresses of the invention are taught as not being liable to release water.

with reference to the relationship between syneresis, strength and flexibility. The sheet devices herein are patches or masks for cosmetic or therapeutic application.

#### Summary of the Invention

The present invention relates to a pre-formed, gel sheet device which is a patch or mask for delivering benefit agents to the skin, hair or nails, comprising from about 30% to about 99.5% of water and a mixture of at least two water-soluble polymeric gel forming agents, wherein the gel comprising the device has an exudate release of greater than 0.7 grams and less than 1.3 grams; a percentage compression at rupture of greater than 45% and less than 90%; and requires a force to rupture of greater than 30 N.

According to a second aspect of the present invention there is provided a cosmetic method of treatment comprising applying to the skin, hair or nails a pre-formed, gel sheet device.

According to a third aspect of the present invention there is provided a pre-formed, gel sheet device comprising a polysaccharide mixture consisting of;

- (i) a red seaweed polysaccharide;
- (ii) a mannose containing polysaccharide;

wherein the device comprises less than 2% total polysaccharide and the ratio of red seaweed polysaccharide to mannose containing polysaccharide is from about 1:1 to about 10:1 and wherein the gel comprising the device requires a force to rupture of greater than 60N.

The pre-formed, gel sheet devices of the present invention show a moderate amount of syneresis, as well as providing excellent in-use characteristics such as unobtrusiveness, conformability, hydration and moisturisation benefits upon topical application. Further, the pre-formed, gel sheet devices of the present invention have excellent mechanical properties and form a high strength structure which is flexible and has a degree of elasticity.

#### Detailed Description of the Invention

The pre-formed, gel sheet devices of the present invention comprise water and a mixture of at least two water-soluble polymeric gel forming agents, as well as various optional ingredients as indicated below. All levels and ratios are by weight of total composition of the device, unless otherwise indicated.

The term "pre-formed" as used herein, means that the device so described is manufactured into a product form having a predetermined thickness, shape and size, wherein the device

### Water-Soluble Polymeric Gel Forming Agents

As an essential component of the pre-formed, gel sheet devices described herein, the devices comprise a mixture of at least two water-soluble polymeric gel forming agents.

In general, the pre-formed, gel sheet devices of the present invention comprise less than 30%, preferably less than 20%, more preferably less than 10% and especially less than 5% by total weight of a mixture of water-soluble polymeric gel forming agents.

Water-soluble polymeric gel forming agents can be self-gelling or may only form gels in combination with other substances such as sugar, alcohol, or mono- or multi- valent salts. Mono- or multi- valent salts may additionally act as gel strengthening agents imparting added strength to the pre-formed, gel sheet devices herein. Suitable cations for the mono- or multi- valent salts may be selected from potassium, sodium, ammonium, zinc, aluminium, calcium and magnesium ions, or mixtures thereof. Suitable anions associated with the aforementioned cations may be selected from chloride, citrates, sulfate, carbonate, borate and phosphate anions, or mixtures thereof.

The water-soluble polymeric gel forming agents for use in the present invention are selected from synthetic or natural polymers, and mixtures thereof.

### Synthetic Polymers

Suitable synthetic polymers for use herein include non-ionic water-soluble polymers; acrylic acid based polymers or derivatives thereof; or cellulose derivatives; and mixtures thereof.

The synthetic polymers useful herein can be categorised by their charge or constituent monomers. However, it is to be understood that the classifications herein are made for the sake of convenience and there may be overlap between the categories.

Non-Ionic Water-Soluble Polymers: Suitable non-ionic water-soluble polymers for use herein include polydimethyl acrylamide, polyvinyl pyrrolidones, polyethylene glycol monomethacrylate, poly-2-ethyl-2-oxazoline, polyvinyl alcohol, polyethylene oxide, polyvinyl ethers, copolymers of polyvinylethers and polyvinylpyrrolidone and derivatives thereof, methyl vinyl ether and maleic anhydride, copolymers of ethylene and maleic anhydride, and mixtures thereof. Further suitable non-ionic water-soluble polymers for use herein include copolymers based on 2-hydroxyethylmethacrylate ("HEMA") which includes the copolymer of "HEMA" and one more comonomers as described in US-A-5,804,107 at column 14, lines 36-67 and column 15, lines 1-34; incorporated herein by reference.

Gelatin: When gelatin is used in the devices herein, a high-molecular weight gelatin is combined with a low-molecular weight one to control the solubility. A gelatin having a low molecular weight of 20,000 or less is poor in gelling ability.

Brown Seaweed Polysaccharides: Polysaccharides which are classified as brown seaweed polysaccharides are isolated by extraction from various species of *Phaeophyceae*. Suitable brown seaweed polysaccharides for use herein include algin, alginic acid, ammonium alginate, calcium alginate, potassium alginate, sodium alginate, propylene glycol alginate, and mixtures thereof.

Red Seaweed Polysaccharides: Polysaccharides which are classified as red seaweed polysaccharides are isolated from marine plant species belonging to the class of *Rhodophyceae*. Red seaweed polysaccharides provide mechanical strength to an aqueous gel. Suitable red seaweed polysaccharides for use in the present invention include agar known in the industry under the (CTFA) trade designation as agar agar flake derived from various *Gelidium* plant species or closely related red algae commercially available as "Agar Agar 100" or "Agar Agar 150" from TIC Gums (Belcamp, MD, USA) or "Agar Agar K-100" from Gumix International Inc. (Fort Lee, NJ, USA); agarose commercially available as "Sea Plaque®" from FMC (Philadelphia, PA, USA) and "Agarose Type 1-b" from Sigma - Aldrich Co. Ltd. (Poole, UK); carrageenan, comprising the fractions lambda-, iota- and kappa- which are the water extracts obtained from various members of the *Gigartinales* or *Solieriales* families, known in the industry under the (CTFA) trade designation as chondrus, commercially available as "Gelcarin® LA", "Seakem® 3/LCM", or "Viscarin® XLV", all from FMC (Philadelphia, PA, USA); and furcellaran commercially available from Gum Technology Corporation (Tucson, Arizona, USA) and Continental Colloids Inc. (Chicago, IL, USA), or mixtures thereof. Preferably, the red seaweed polysaccharide for use herein is selected from agar, agarose, kappa-carrageenan and furcellaran, or mixtures thereof. More preferably, the red seaweed polysaccharide for use herein is selected from agar and agarose, or mixtures thereof.

Glucomannan: Glucomannans are mannose containing polysaccharides which comprise an essentially linear backbone of  $\beta$  (1 $\rightarrow$ 4)-linked glucose and mannose residues. The C-6 position of a mannose or glucose residue in the polysaccharide backbone may be substituted with an acetyl group. The acetyl groups are generally found on one per six sugar residues to one per twenty sugar residues. Suitable glucomannans or derivatives thereof for use herein have a ratio of mannose to glucose of from about 0.2 to about 3. Preferred glucomannans for use herein include konjac mannan, which is the generic name for the flour formed from grinding the tuber root of the *Amorphophallus konjac* plant

welan gum; dextran, commercially available as "Sephadex G-25" from Pharmacia Fine Chemicals (Piscataway, NJ, USA) and derivatives thereof; and sclerotium gum, commercially available as "Amigel" from Alban Muller International (Montreuil, France), or mixtures thereof. Preferably, the fermentation polysaccharide or derivative thereof is selected from gellan gum and xanthan gum, or mixtures thereof. More preferably, the fermentation polysaccharide is xanthan gum.

Extracts of Marine Invertebrates: Polysaccharides derived from marine invertebrates, specifically the exoskeleton of such invertebrates, consist chiefly of N-acetyl-D-glucosamine residues. Examples of such polysaccharides suitable for use herein include; chitosan, commercially available for example as "Marine Dew" from Ajinomoto (Teakneck, NJ, USA); and hydroxypropyl chitosan commercially available for example as "HPCH Liquid" from Ichimaru Pharcos (Yamagata Gun Gifu-Pref, Japan) and derivatives; or mixtures thereof.

Starch or Derivatives thereof: Starches are polysaccharides which consist of various proportions of two glucose polymers, amylose and amylopectin. Suitable materials for use herein include starch; amylopectin; and dextrin commercially available as "Nadex 360" from National Starch (Bridgewater, NJ, USA) and derivatives; or mixtures thereof.

Natural Fruit Extracts: Examples of natural fruit extracts suitable for use herein include pectin; and arabian; or mixtures thereof.

Plant Fiber Derivatives: A suitable example of a plant fiber derivative for use herein is cellulose.

Natural Plant Exudates: Suitable polysaccharides obtained from natural plant exudates for use herein include karaya gum, tragacanth gum, arabic gum, tamarind gum, and ghatty gum, or mixtures thereof.

Resinous Gums: Examples of resinous gums suitable for use herein include shellac gum which is obtained from the resinous secretion of the insect *Laccifer (Tachardia) lacca*; damar gum; copal gum and rosin gum; or mixtures thereof.

Preferably, the mixture of at least two water-soluble polymeric gel forming agents of the present invention forms solid, self-supporting and self-adhesive structures. In general, gels formed from a single water-soluble polymeric gel forming agent may demonstrate one or two of the desirable physical properties described herein, but not all three. Gels formed from synthetic polymers *per se* are often slow setting and require water to be driven out of the reaction mixture before a continuous gel phase will form. As a result, the

polymeric gel forming agent mixture herein may comprise one or more polysaccharides and a non-ionic water-soluble polymer, or alternatively, it may comprise two or more polysaccharides. More preferably, the mixture of at least two water-soluble polymeric gel forming agents is a polysaccharide mixture. Preferably, the polysaccharide mixture comprises (1) at least one red seaweed polysaccharide; brown seaweed polysaccharide; or mixtures thereof; and (2) at least one fermentation polysaccharide; galactomannan; glucomannan; natural plant exudate; or natural fruit extract; and derivatives or mixtures thereof. More preferably, the polysaccharide mixture comprises (1) at least one red seaweed polysaccharide, and; (2) at least one fermentation polysaccharide; galactomannan; glucomannan; and derivatives or mixtures thereof.

In a preferred embodiment, the mixture of at least two water-soluble polymeric gel forming agents of the present invention is a polysaccharide mixture consisting of, (1) a red seaweed polysaccharide and (2) a mannose containing polysaccharide wherein the device comprises less than 2% total polysaccharide. Preferably, the red seaweed polysaccharide is selected from agar and agarose, or mixtures thereof and wherein preferably the mannose containing polysaccharide is selected from a galactomannan, glucomannan and derivatives, or mixtures thereof. Without wishing to be limited by theory, it is believed that the galactomannan or glucomannan in the polysaccharide mixture complements the red seaweed polysaccharide, and contributes to the mechanical strength and flexibility of the pre-formed, gel sheet devices of the present invention. This synergy is believed to arise due to the interactions between the polysaccharides. Red seaweed polysaccharides form double helical structures and glucomannans and galactomannans have areas of relative un-substitution on the polymer backbone. These areas of relative un-substitution on the galactomannan and glucomannan backbone synergistically interact with the helices of the red seaweed polysaccharides. The polysaccharide mixture may additionally comprise xanthan gum in amounts less than or equal to the amount of mannose containing polysaccharide. Further, from the viewpoint of providing improved mechanical properties and a moderate amount of syneresis from a pre-formed, gel sheet device, preferably, the ratio of red seaweed polysaccharide to mannose containing polysaccharide is from about 1:1 to about 10:1 and more preferably from about 2:1 to about 7:1.

The pre-formed, gel sheet devices of the present invention display a moderate amount of syneresis and preferably, the devices herein are moist to the touch. As afore-mentioned, while a device comprising a gel will always undergo some syneresis, an excessive amount of syneresis results in an ineffective and unattractive product. In order to evaluate what is



The benefit agents include their pharmaceutically-acceptable salts and by "pharmaceutically-acceptable salts" are meant any of the commonly-used salts that are suitable for use in contact with the tissues of humans without undue toxicity, irritation, incompatibility, instability, irritation, allergic response, and the like.

In general, the pre-formed, gel sheet devices of the present invention comprise from about 0.01% to about 40%, preferably from about 0.05% to about 30% and most preferably from about 0.1% to about 20% by weight of the device of at least one benefit agent, or mixtures thereof.

The benefit agents useful herein can be categorised by their therapeutic benefit or their postulated mode of action. However, it is to be understood that the benefit agents useful herein can in some instances provide more than one therapeutic benefit or operate via more than one mode of action. Therefore, classifications herein are made for the sake of convenience and are not intended to limit the benefit agent to that particular application or applications listed. The following benefit agents are useful in the pre-formed, gel sheet devices of the present invention.

Anti-Acne Actives: Anti-acne actives can be effective in treating and preventing *acne vulgaris*, a chronic disorder of the pilosebaceous follicles. The condition involves inflammation of the pilosebaceous apparatus thereby resulting in lesions, which may include papules, pustules, cysts, comedones, and severe scarring. The bacteria *Corynebacterium acnes* and *Staphylococcus epidermis* are usually present in the pustular contents. Examples of useful anti-acne actives include the keratolytics described in WO98/18444. Further useful actives include retinoids such as retinoic acid (e.g., cis and/or trans) and its derivatives (e.g., esters); retinol and its esters (e.g., retinyl propionate, retinyl acetate); abietic acid, adapalene, tazarotene, allantoin, aloe extracts, arbiotic acid and its salts, ASEBIOL (available from Laboratories Serobiologiques located in Somerville, NJ), azaleic acid, barberry extracts, bearberry extracts, belamcanda chinensis, benzoquinolinones, benzoyl peroxide, berberine, BIODERMINE (available from Sederma located in Brooklyn, NY), bioflavonoids as a class, bisabolol, s-carboxymethyl cysteine, carrot extracts, cassia oil, clove extracts, citral, citronellal, climazole, COMPLETECH MBAC-OS (available from Lipo, located in Paterson, NJ), CREMOGEN M82 (available from Dragoco, located in Totowa, NJ), cucumber extracts, dehydroacetic acid and its salts, dehydroepiandrosterone and its sulfate derivative, dichlorophenyl imidazolidioxolan, d,l-valine and its esters, DMDM hydantoin, erythromycin, escinol, ethyl hexyl monoglyceryl ether, ethyl 2-hydroxy undecanoate, farnesol, farnesyl acetate, geraniol, geranyl geraniol, glabridin, gluconic acid, gluconolactone, glyceryl monocaprates, glycolic

agents and accelerators include glucose tyrosinate and acetyl tyrosine, brazilin, caffeine, coffee extracts, DNA fragments, isobutyl methyl xanthine, methyl xanthine, PHOTOTAN (available from Laboratoires Serobiologiques located in Somerville, NJ), prostaglandins, tea extracts, theophylline, UNIPERTAN P2002 (available from Unichem, located in Chicago, IL) and UNIPERTAN P27 (available from Unichem, located in Chicago, IL); and mixtures thereof. Further useful artificial tanning agents herein are described in WO98/18444.

Antiseptics: Examples of suitable antiseptics for use herein include alcohols, benzoate, sorbic acid, and mixtures thereof.

Anti-microbial and Anti-fungal Actives: Anti-microbial and anti-fungal actives can be effective to prevent the proliferation and growth of bacteria and fungi. Non-limiting examples of antimicrobial and antifungal actives include ketoconazole, ciclopirox, benzoyl peroxide, tetracycline, azelaic acid and its derivatives, ethyl acetate, alantolactone, isosalantolactone, alkanet extract (alaninin), anise, arnica extract (helenalin acetate and 11, 13 dihydrohelenalin), aspidium extract (phloro, lucinol containing extract), barberry extract (berberine chloride), bay sweet extract, bayberry bark extract (myricitrin), benzalkonium chloride, benzethonium chloride, benzoic acid and its salts, benzoin, benzyl alcohol, blessed thistle, bletilla tuber, bloodroot, bois de rose oil, burdock, butyl paraben, cade oil, CAE (available from Ajinomoto located in Teaneck, NJ), cajeput oil, cangzhu, caraway oil, cascarilla bark (sold under the trade name ESSENTIAL OIL), cedarleaf oil, chamomille, chaparral, chlorophenesin, chlorxylenol, cinnamon oil, citronella oil, clove oil, dehydroacetic acid and its salts, dill seed oil, DOWICIL 200 (available from Dow Chemical located in Midland, MI), echinacea, elenolic acid, epimedium, ethyl paraben, FO-TI, galbanum, garden burnet, GERMALL 115 and GERMALL II (available from ISP-Sutton Labs located in Wayne, NJ), german chamomile oil, giant knotweed, GLYDANT (available from Lonza located in Fairlawn NJ), GLYDANT PLUS (available from Lonza located in Fairlawn, NJ), grapefruit seed oil, hexamidine diisethionate, hinokitiol, honey, honeysuckle flower, hops, immortelle, IODOPROPYNYL BUTYL CARBAMIDE (available from Lonza located in Fairlawn, NJ), isobutyl paraben, isopropyl paraben, JM ACTICARE (available from Microbial Systems International located in Nottingham, UK), juniper berries, KATHON CG (available from Rohm and Haas located in Philadelphia, PA, USA), labdanum, lavender, lemon balm oil, lemon grass, methyl paraben, mint, mume, mustard, myrrh, neem seed oil, ortho phenyl phenol, OLIVE LEAF EXTRACT (available from Bio Botanica, located in Hauppauge, NY), parsley, patchouli oil, peony root, PHENONIP (available from Nipa Labs located in

jujube, kola extract, LANACHRYS 28 (available from Lana Tech, located in Paris, France), lemon oil, lianqiao, licorice root, ligusticum, ligustrum, lovage root, luffa, mace, magnolia flower, manjistha extract, margaspidin, margaspidin, matricin, MICROAT IRC (available from Nurture, located in Missoula, MT) mints, mistletoe, MODULENE (available from Seporga, located in Sophia Antipolis, France), mung bean extract, musk, oat extract, orange, panthenol, papain, peony bark, peony root, PHYTOPLENOLIN (available from Bio Botanica, located in Hauppauge, NY), PREREGEN (available from Pentapharm, located in Basel, Switzerland), purslane, QUENCH T (available from Centerchem, located in Stamford, CT), quillaia, red sage, rehmannia, rhubarb, rosemary, rosmarinic acid, royal jelly, rue, rutin, sandalwood, sanqi, sarsaparilla, saw palmetto, SENSILINE (available from Silab, located in Brive, France), SIEGESBECKIA (available from Sederma, located in Brooklyn, NY), stearyl glycyrrhetinate, STIMUTEX (available from Pentapharm, located in Basel, Switzerland), storax, sweet birch oil, sweet woodruff, tagetes, tea extract, thyme extract, tienchi ginseng, tocopherol, tocopheryl acetate, triclosan, turmeric, urimei, ursolic acid, white pine bark, witch hazel, xinyi, yarrow, yeast extract, yucca, and mixtures thereof.

Sunscreening Agents: Examples of suitable sunscreening agents useful herein are described in WO98/18444, incorporated herein by reference. Further examples of sunscreens which are useful herein include diethanolamine p-methoxycinnamate, dioxybenzone, ethyl dihydroxypropyl PABA, glyceryl aminobenzoate, lawsome and dihydroxyacetone, menthyl anthranilate, methyl anthranilate, octyl dimethyl PABA, red petroleum, sulisobenzene, triethanolamine salicylate, and mixtures thereof.

Skin Barrier Repair Aids: Skin barrier repair aids are those skin care aids which can help repair and replenish the natural moisture barrier function of the epidermis. Suitable examples of skin barrier repair aids include brassicasterol, caffeine, campesterol, canola derived sterols, CERAMAX (available from Quest, located in Ashford, England), CERAMIDE 2 (available from Sederma, located in Brooklyn, NY), CERAMIDE HO3TM (available from Sederma, located in Brooklyn, NY), CERAMIDE II (available from Quest, located in Ashford, England), CERAMIDE III (available from Quest, located in Ashford, England), CERAMIDE IIIB (available from Cosmoform, located in Delft, Netherlands), CERAMIDE IS 3773 (available from Laboratories Serobiologiques, located in Somerville, NJ), CERAMINOL (available from Inocosm, located in Chatenay Malabry, France), CERASOL (available from Pentapharm, located in Basel, Switzerland), CEPHALIP (available from Pentapharm, located in Basel, Switzerland), cholesterol, cholesterol hydroxystearate, cholesterol isostearate, 7-dehydrocholesterol, DERMATEIN

benzoate, ASC III (available from E. Merck, located in Darmstadt, Germany), ascorbic acid, ascorbyl palmitate, asiatic acid, asiaticosides, ARLAMOL GEO (available from ICI, located in Wilmington, DE), azaleic acid, benzoic acid derivatives, bertholletia extracts, betulinic acid, BIOCHANIN A, BIOPEPTIDE CL (available from Sederma, located in Brooklyn, NY) BIOPEPTIDE EL (available from Sederma, located in Brooklyn, NY), biotin, blackberry bark extract, blackberry lily extracts, black cohosh extract, blue cohosh extract, butanoyl betulinic acid, catecholamines, chalcones, chaste tree extract, cis retinoic acid, citric acid esters, clover extracts, coenzyme Q10 (ubiquinone), coumestrol, CPC PEPTIDE (Barnet Products, located in Englewood, NJ), daidzein, dang gui extract, darutoside, debromo laurinterol, 1-decanoyl-glycero-phosphonic acid, dehydrocholesterol, dehydrodicreosol, dehydrodieugenol, dehydroepiandrosterone, DERMOLECTINE (available from Sederma, located in Brooklyn, NY), dehydroascorbic acid, dehydroepiandrosterone sulfate, dianethole, 2,4-dihydroxybenzoic acid, diosgenin, disodium ascorbyl phosphate, dodecanedioic acid, EDERLINE (available from Seporga, located in Sophia Antipolis, France), ELESERYL SH (available from Laboratories Serobiologiques, located in Somerville, NJ), ENDONUCLEINE (available from Laboratories Serobiologiques, located in Somerville, NJ), equol, ergosterol, eriodictyol, estrogen and its derivatives, ethocyn, eythrobic acid, farnesol, farnesyl acetate, fennel extract, FIBRASTIL (available from Sederma, located in Brooklyn, NY), FIBROSTIMULINES S AND P (available from Sederma, located in Brooklyn, NY), FIRMOGEN IS 8445 (available from Laboratories Serobiologiques, located in Somerville, NJ), flavonoids (especially flavanones such as unsubstituted flavanone and chalcones such as unsubstituted chalcone and monohydroxy and dihydroxy chalcones), formononetin, forsythia fruit extract, gallic acid esters, gamma amino butyric acid, GATULINE RC (available from Gattlefosse, located in Saint Priest, France), genistein, genisteine, genistic acid, gentisyl alcohol, ginkgo bilboa extracts, ginseng extracts, ginsenoside, RO, R<sub>6-1</sub>, R<sub>6-2</sub>, R<sub>6-3</sub>, R<sub>C</sub>, R<sub>D</sub>, R<sub>E</sub>, R<sub>F</sub>, R<sub>F-2</sub>, R<sub>G-1</sub>, R<sub>G-2</sub>, gluco pyranosyl-l-ascorbate, glutathione and its esters, glycitein, eptyloxy 4 salicylic acid, hesperitin, hexahydro curcumin, HMG-Coenzyme A Reductase Inhibitors, hops extracts, 11 hydroxy undecanoic acid, 10 hydroxy decanoic acid, 25-hydroxycholesterol, ISOFAVONE SG 10 (available from Barnet Products, located in Englewood, NJ), kinetin, L-2-oxo-thiazolidine-4-carboxylic acid esters, lactate dehydrogenase inhibitors, 1-lauryl-, lyso-phosphatidyl choline, lectins, LICHOCHALCONE LR15 (available from Maruzen, located in Morristown, NJ), licorice extracts, lipoic acid, lumisterol, luteolin, magnesium ascorbyl phosphate, melatonin, melibiose, metalloproteinase inhibitors, methoprene, methoprenic acid, 4-methoxy salicylic acid, mevalonic acid, MPC COMPLEX (available

pyranosyl-l-ascorbate, gluconic acid, glucosamine, glycolic acid, glycyrrhizinic acid, green tea extract, 4-hydroxy-5-methyl-3[2h]-furanone, hydroquinine, 4-hydroxyanisole and its derivatives, 4-hydroxy benzoic acid derivatives, hydroxycaprylic acid, inositol ascorbate, kojic acid, lactic acid, lemon extract, licorice extract, LICORICE P-TH (available from Barnet Products, located in Englewood, NJ), linoleic acid, magnesium ascorbyl phosphate, MELFADE (available from Pentapharm, located in Basel, Switzerland), MELAWHITE (available from Pentapharm, located in Basel, Switzerland), morus alba extract, mulberry root extract, niacinamide, nicotinic acid and its esters, nicotinyl alcohol, 5-octanoyl salicylic acid, parsley extract, phellinus linteus extract, placenta extract, pyrogallol derivatives, retinoic acid, retinol, retinyl esters (acetate, propionate, palmitate, linoleate), 2,4 resorcinol derivatives, 3,5 resorcinol derivatives, rose fruit extract, rucinol, salicylic acid, song-yi extract, SOPHORA POWDER (available from Barnet Products, located in Englewood, NJ), 4-thioresorein, 3, 4, 5 trihydroxybenzyl derivatives, tranexamic acid, TYROSLAT 10,11 (available from Fytokem), vitamin D<sub>3</sub> and its analogs, yeast extract, or mixtures thereof.

Sebum Inhibitors: Sebum inhibitors can decrease the production of sebum in the sebaceous glands. Examples of suitable sebum inhibitors include aluminium hydroxy chloride, ASEBIOL (available from Laboratories Serobiologiques, located in Somerville, NJ), BIODERMINE (available from Sederma, located in Brooklyn, NY), climbazole, COMPLETECH MBAC-OS (available from Lipo, located in Peterson, NJ), corticosteroids, cucumber extracts, dehydroacetic acid and its salts, dichlorophenyl imidazoldioxolan, ketoconazole, LICHOCALCONE LR 15 (available from Maruzen), niacinamide, nicotinic acid and its esters, nicotinyl alcohol, phloretin, PHLOROGINE (available from Secma, located in Pontrieux, France), pyridoxine and derivatives thereof, s-carboxymethyl cysteine, SEPICONTROL AS, spironolactone, tiroxolone, tocopherol, UNTRIENOL T27 (available from Unichem, located in Chicago IL), and ZINCIDONE (available from UCIB, located in Clifton, NJ), or mixtures thereof.

Sebum Stimulators: Sebum stimulators can increase the production of sebum by the sebaceous glands. Non-limiting examples of sebum stimulators include bryonolic acid, COMPLETECH MBAC-DS (available from Lipo, located in Paterson, NJ), dehydroepiandrosterone (also known as DHEA), orizanol, and mixtures thereof.

Skin Sensates: Non-limiting examples of suitable skin sensates for use herein include agents which impart a cool feel such as camphor, thymol, 1-menthol and derivatives thereof, eucalyptus, carboxamides; menthane ethers and menthane esters; and agents imparting a warm feel such as cayenne tincture, cayenne extract, cayenne powder, vanillylamide nonanoate, nicotinic acid derivatives (benzyl nicotinate, methyl nicotinate,

Agents for Inhibiting Hair Growth: Non-limiting examples of suitable agents for inhibiting hair growth include 17 beta estradiol, adamantyguanidines, adamantylamidines, adenylosuccinate synthase inhibitors, anti angiogenic steroids, aspartate transcarbamylase inhibitors, betamethasone valerate, bisabolol, copper ions, curcuma extract, cyclooxygenase inhibitors, cysteine pathway inhibitors, dehydroacetic acid, dehydroepiandrosterone, diopiros leak extract, epidermal growth factor, epigallocatechin, essential fatty acids, evening primrose oil, gamma glutamyl transpeptidase inhibitors, ginger oil, glucose metabolism inhibitors, glutamine metabolism inhibitors, glutathione, green tea extracts, heparin, KAPILANNE (available from International Sourcing Distributor, located in Upper Saddle River, NJ), L, 5 diaminopentanoic acid, L-asparagine synthase inhibitors, linoleic acid, lipoxygenase inhibitors, longa extract, mimosinamine dihydrochloride, mimosine, nitric oxide synthase inhibitors, non steroidal anti-inflammatories, ornithine decarboxylase inhibitors, ornithine aminotransferase inhibitors, panthenol, phorhetur, phosphodiesterase inhibitors, pleione extract, protein kinase C inhibitors, 5-alpha reductase inhibitors, sulfhydryl reactive compounds, tiroxolone, transforming growth factor beta 1, urea, zinc ions, and mixtures thereof.

5 - Alpha Reductase Inhibitors: Non-limiting examples of 5-alpha reductase inhibitors include CLOVE 55 (available from Barnet Products Distributor located in Englewood, NJ), ethynylestradiol, genisteine, genistine, Licochalcone LR-15, saw palmetto extracts, SOPHORA EXTRACT (available from Maruzen located in Morristown, NJ), ZINCIDONE (available from UCIB, located in Clifton, NJ), and mixtures thereof.

Desquamation Enzyme Enhancers: These agents enhance the activity of endogenous desquamating enzymes. Non-limiting examples of desquamation enzyme enhancers include, N-methyl serine, serine, trimethyl glycine, and mixtures thereof.

Anti Glycation Agents: Anti-glycation agents prevent the sugar induced crosslinking of collagen. A suitable example of an anti-glycation agent includes AMADORINE (available from Barnet Products Distributor located in Englewood, NJ).

Preferred examples of benefit agents useful herein include those selected from the group consisting of salicylic acid, niacinamide, tocopheryl nicotinate, benzoyl peroxide, 3-hydroxy benzoic acid, flavonoids (e.g., flavanone, chalcone), farnesol, phytantriol, glycolic acid, lactic acid, 4-hydroxy benzoic acid, acetyl salicylic acid, 2-hydroxybutanoic acid, 2-hydroxypentanoic acid, 2-hydroxyhexanoic acid, cis-retinoic acid, trans-retinoic acid, retinol, retinyl esters (e.g., retinyl propionate), phytic acid, N-acetyl-L-cysteine, lipoic acid, tocopherol and its esters (e.g., tocopheryl acetate), azelaic acid, arachidonic acid, tetracycline, ibuprofen, naproxen, ketoprofen, hydrocortisone, acetaminophen,

panthenol, polyethylene glycol and derivatives thereof (such as PEG 15 butanediol, PEG 4, PEG 5 pentaerythritol, PEG 6, PEG 8, PEG 9), pentaerythritol, 1,2 pentanediol, PPG-1 glyceryl ether, PPG-9, 2-pyrrolidone-5-carboxylic acid and its salts such as glyceryl pca, saccharide isomerate, SEACARE (available from Secma), sericin, silk amino acids, sodium acetylhyaluronate, sodium hyaluronate, sodium poly-aspartate, sodium polyglutamate, sorbeth 20, sorbeth 6, sugar and sugar alcohols and derivatives thereof such as glucose, mannose and polyglycerol sorbitol, trehalose, triglycerol, trimethylpropane, tris (hydroxymethyl) amino methane salts, and yeast extract, or mixtures thereof.

Preferably, the humectants for use herein are selected from glycerine, butylene glycol, hexylene glycol, panthenol and polyethylene glycol and derivatives thereof, or mixtures thereof.

#### Emulsifiers/Surfactants

The pre-formed, gel sheet devices of the present invention can also optionally comprise one or more surfactants and/or emulsifiers. Emulsifiers and/or surfactants, generally help to disperse and suspend the discontinuous phase within the continuous phase. A surfactant may also be useful if the product is intended for skin, hair or nail cleansing. For convenience hereinafter emulsifiers will be referred to under the term 'surfactants', thus 'surfactant(s)' will be used to refer to surface active agents whether used as emulsifiers or for other surfactant purposes such as skin, hair or nail cleansing. Known or conventional surfactants can be used in the composition, provided that the selected agent is chemically and physically compatible with essential components of the composition, and provides the desired characteristics. Suitable surfactants include silicone materials, non-silicone materials, and mixtures thereof.

The compositions of the present invention preferably comprise from about 0.01% to about 15% of a surfactant or mixture of surfactants. The exact surfactant or surfactant mixture chosen will depend upon the pH of the composition and the other components present.

Preferred surfactants are nonionic. Among the nonionic surfactants that are useful herein are the condensation products of alkylene oxides with fatty acids (i.e. alkylene oxide esters of fatty acids). These materials have the general formula  $\text{RCO}(\text{X})_n\text{OH}$  wherein R is a  $\text{C}_{10-30}$  alkyl group, X is  $-\text{OCH}_2\text{CH}_2-$  (i.e. derived from ethylene glycol or oxide) or  $-\text{OCH}_2\text{CHCH}_3-$  (i.e. derived from propylene glycol or oxide), and n is an integer from about 6 to about 200. Other nonionic surfactants are the condensation products of alkylene oxides with 2 moles of fatty acids (i.e. alkylene oxide diesters of fatty acids).

ethers of C<sub>1</sub>-C<sub>30</sub> fatty alcohols, polyglyceryl esters of C<sub>1</sub>-C<sub>30</sub> fatty acids, C<sub>1</sub>-C<sub>30</sub> esters of polyols, C<sub>1</sub>-C<sub>30</sub> ethers of polyols, alkyl phosphates, polyoxyalkylene fatty ether phosphates, fatty acid amides, acyl lactylates, and mixtures thereof. Examples of these non-silicon-containing surfactants include: polysorbate 20, polyethylene glycol 5 soya sterol, steareth-20, cetareth-20, PPG-2 methyl glucose ether distearate, polysorbate 80; polysorbate 60, available under the trade name "Tween 60" from ICI (Wilmington, MA, USA); glyceryl stearate, sorbitan monolaurate, polyoxyethylene 4 lauryl ether sodium stearate, polyglyceryl-4 isostearate, hexyl laurate, PPG-2 methyl glucose ether distearate, and mixtures thereof.

Preferred among the nonionic surfactants are those selected from cetareth-12, sucrose cocoate, steareth-100, polysorbate 60, PEG-60 Hydrogenated Castor Oil, isoceteth-20, oleth-20, PEG-100 stearate, and mixtures thereof.

Other suitable emulsifiers for use herein are polyoxypropylene, polyoxyethylene ethers of fatty alcohols. These materials have the general formula  $R(\text{CH}_2\text{CHCH}_3\text{O})_x-(\text{CH}_2\text{CH}_2\text{O})_y\text{-H}$ , wherein R is an OC<sub>10</sub>-C<sub>30</sub> alkyl group or C<sub>10</sub>-C<sub>30</sub> alkyl group, x has an average value from 1 to 20 and y has an average value from 1 to 30, examples of which include PPG-6-Decyltetradeceth-30, available under the trade name "Pen 4630" from Nikko Chemicals Co. Ltd. (Tokyo, Japan); PPG-6-Decyltetradeceth-20, available under the trade name "Pen 4620" from Nikko Chemicals Co. Ltd. (Tokyo, Japan); and PPG-5-Ceteth-20, available under the trade name "Procetyl AWS" from Croda Chemicals Ltd. (Goole, North Humberside, England).

Another emulsifier useful herein are fatty acid ester blends based on a mixture of sorbitan or sorbitol fatty acid ester and sucrose fatty acid ester, as described in more detail in WO98/22085, incorporated by reference herein.

The hydrophilic surfactants useful herein can alternatively or additionally include any of a wide variety of cationic, anionic, zwitterionic, and amphoteric surfactants such as are known in the art. See, e.g., McCutcheon's, Detergents and Emulsifiers, North American Edition (1986), published by Allured Publishing Corporation; US-A-5,011,681 to Ciotti et al., issued April 30, 1991; US-A-4,421,769 to Dixon et al., issued December 20, 1983; and US-A-3,755,560 to Dickert et al., issued August 28, 1973; these four references are incorporated herein by reference in their entirety.

A wide variety of cationic surfactants are useful herein. Suitable cationic surfactants for use herein are disclosed in WO98/18444.



diglycerides of C1-C30 carboxylic acids, triglycerides of C1-C30 carboxylic acids, ethylene glycol monoesters of C1-C30 carboxylic acids, ethylene glycol diesters of C1-C30 carboxylic acids, propylene glycol monoesters of C1-C30 carboxylic acids, propylene glycol diesters of C1-C30 carboxylic acids, C1-C30 carboxylic acid monoesters and polyesters of sugars, polydialkylsiloxanes, polydiarylsiloxanes, polyalkarylsiloxanes, cyclomethicones having 3 to 9 silicon atoms, vegetable oils, hydrogenated vegetable oils, polypropylene glycol C4-C20 alkyl ethers, di C8-C30 alkyl ethers, and mixtures thereof.

These agents are described in more detail in WO98/18444, which is incorporated herein by reference.

#### Other Optional Ingredients

The compositions of the present invention can comprise a wide range of other optional components. These additional components should be pharmaceutically acceptable. The CTFA Cosmetic Ingredient Handbook: Second Edition, 1992, which is incorporated by reference herein in its entirety, describes a wide variety of non-limiting cosmetic and pharmaceutical ingredients commonly used in the cosmetic industry, which are suitable for use in the compositions of the present invention. Non-limiting examples of functional classes of ingredients are described at page 537 of this reference. Examples of these and other functional classes include: abrasives, absorbents, antibiotics, anticaking agents, anti-dandruff agents, anti-perspirant agents, antioxidants, vitamins, biological additives, bleach, bleach activators, brighteners, builders, buffering agents, chelating agents, chemical additives, colorants, cosmetics, cleansers, cosmetic astringents, cosmetic biocides, denaturants, dental treatments, deodorants, desquamation actives, depilatories, drug astringents, dyes, dye transfer agents, enzymes, external analgesics, flavors, film formers, fragrance components, insect repellants, mildewcides, opacifying agents, oxidative dyes, oxidising agents, pest control ingredients, pH adjusters, pH buffers, pharmaceutical actives, plasticizers, preservatives, radical scavengers, skin, hair or nail bleaching agents, skin, hair or nail conditioners, skin, hair or nail penetration enhancers, stabilisers, surface conditioners, reducing agents, temperature depressors, and warmth generators.

Also useful herein are aesthetic components such as colorings, essential oils, and skin, hair or nail healing agents.

Other optional materials herein include pigments. Pigments suitable for use in the compositions of the present invention can be organic and/or inorganic. Also included within the term pigment are materials having a low colour or lustre such as matte

ends may communicate with each other, or its length may be shortened so as to only wrap partially around. In either case, the wraps should exhibit excellent conformity to the shape of the body part. Typically, such body parts will include the user's back, upper arm, lower arm, upper leg, lower leg, neck, and torso.

Following application of the device, it may be left on the target area for about 3 hours, preferably about 1 hour, more preferably less than 15 minutes. The pre-formed, gel sheet device can then be removed all in one piece.

Depending on the benefit agent (or benefit agents) contained therein, the pre-formed, gel sheet devices of the present invention may have at least one of the following uses; hydrating the skin, hair or nails, smoothing fine lines and wrinkles; cosmetically treating acne; firming the skin; strengthening; softening; exfoliating; improving and/or evening skin tone and/or texture; skin, hair or nail lightening; conditioning the skin or hair; tanning; reducing the appearance of pores; absorbing or controlling secretions; protecting and/or soothing the skin, hair or nails, muscles, aches or pains; reducing puffiness, and/or dark circles; stimulating wound healing; warming, refreshing or cooling the skin; relieving inflammation; brightening the complexion; decongesting; reducing swelling; treating dermatological conditions; cushioning; purifying; fragrancng; reducing bacterial or micro-organism growth; healing; repelling insects; removing unwanted hair, dirt, or make-up; and colouring or bleaching the target area to which the device is applied. Preferably, the pre-formed, sheet devices herein are used for hydrating the skin, hair or nails; smoothing fine lines and wrinkles; and improving and/or evening skin tone and/or texture.

## Methods

### Exudate Release Test

The amount of syneresis from a pre-formed, gel sheet device of the present invention is measured on a gel comprising the device via an exudate release test.

Data on exudate release from gels referenced herein were generated by the following method. A gel formulation of interest is prepared as described below. While still a hot liquid ( $>80^{\circ}\text{C}$ ), nine grams ( $\pm 0.1$  g) is poured into a 91 mm diameter shallow receptacle, e.g. the lid of a Falcon-1029 Petri dish. This receptacle is hermetically sealed to reduce evaporative losses. The gel is allowed to solidify undisturbed with cooling to room temperature. The gel is stored at room temperature overnight before readings are taken. The covering is removed and the receptacle with sample tared ( $\pm 0.005\text{g}$ ). Three pieces of filter paper (9.0 cm Whatman-114 Wet Strengthened) are stacked on the flat gel

% Compression =  $\frac{\text{distance travelled by plate (measured in mm) at maximum force}}{12 \text{ mm (original moulded sample height)}} \times 100$

12 mm (original moulded sample height)

If gel rupture has not occurred by the end of the 10.8 mm stroke, (i.e. 90% compression), the gel is classified as 'non-rupturing' under these test conditions.

#### Examples

The invention is illustrated by the following examples.

#### Examples 1 - 6

Ingredient	E.G. 1 %w/w	E.G.2 %w/w	E.G. 3 %w/w	E.G. 4 %w/w	E.G. 5 %w/w	E.G. 6 %w/w
Agar	0.6	0.4	-	-	0.6	0.4
Agarose	0.3	0.4	0.75	0.8	-	-
Kappa-Carrageenan	-	-	-	-	0.3	-
Locust Bean Gum	0.1	-	-	-	-	-
Konjac Mannan	0.2	-	0.1	-	0.3	0.3
Xanthan Gum	0.1	-	-	-	-	0.1
Kelgum™ <sup>1</sup>	-	0.3	0.3	0.3	-	-
Polyvinyl Pyrrolidone	-	2.0	-	-	-	-
Glycerin	15.0	25.0	20.0	15.0	20.0	10.0
Butylene Glycol	-	-	5.0	8.0	5.0	-
Panthenol	3.0	-	2.0	2.0	-	-
Niacinamide	-	-	10.0	-	-	-
Sucrose	-	-	-	0.5	-	-
Polycottonseedate	-	-	-	-	-	-
Polysorbate 60	0.08	-	-	0.2	-	-
Dimethicone Copolyol	-	-	0.02	-	0.02	-
Benzyl Alcohol	0.3	0.2	-	0.2	-	0.2
Phenoxyethanol	-	-	-	-	0.3	0.1
Ethyl Paraben	0.1	-	0.2	-	-	-
Propyl Paraben	0.05	-	-	-	-	-
Disodium EDTA	-	-	0.1	-	0.1	-
Water	to 100	to 100	to 100	to 100	to 100	to 100
<b>Exudate Release(g)</b>	<b>0.76</b>	<b>0.83</b>	<b>0.99</b>	<b>0.84</b>	<b>0.93</b>	<b>1.04</b>
<b>Force To Rupture(N)</b>	<b>78</b>	<b>63</b>	<b>114</b>	<b>102</b>	<b>55</b>	<b>49</b>
<b>% Compression</b>	<b>58</b>	<b>52</b>	<b>67</b>	<b>58</b>	<b>63</b>	<b>76</b>

1. Kelgum™ is a 1:1 mixture of xanthan gum and locust bean gum supplied by Kelco, San Diego, CA, USA.

The polysaccharide gums are mixed with water to form a uniform dispersion (this can be facilitated by pre-dispersing the polysaccharides in a non-solvent e.g. polyhydric alcohol)

Examples 7 - 14 are comparative examples of gel patches described in the literature, and the gels are prepared according to the methods outlined in Examples 1-6 herein. Measurements are taken on the exudate release from the gel compositions, the percentage compression at the point of rupture and the force required to rupture the gel for each example, and the results obtained from these measurements are shown.

As can be seen from these comparative examples, whilst most of the gels comprising the patches discussed in the literature meet one or two of the parameters described by the present invention, none of the gels of the examples have a desirable amount of syneresis, strength and flexibility.

Ingredient (% w/w)	E.G. 7	E.G. 8	E.G. 9	E.G. 10	E.G. 11	E.G. 12	E.G. 13	E.G. 14
Agarose	-	-	-	-	2.0	-	-	-
Kappa-Carrageenan	-	-	-	1.0	-	3.0	2.0	0.3
Locust Bean Gum	-	-	-	-	-	-	2.0	0.3
Xanthan Gum	-	-	-	0.5	-	-	-	-
Kelgum™ <sup>1</sup>	-	1.0	-	-	-	-	-	-
Gellan Gum	1.0	-	0.7	-	-	-	-	-
Glycerin	10.0	10.0	25.0	20.0	20.0	30.0	10.0	-
Orgasol 2002D <sup>2</sup>	-	-	-	2.0	-	-	-	-
Ethyl Paraben	-	-	-	-	0.2	0.2	0.15	-
Disodium EDTA	-	-	-	-	0.1	0.1	0.1	-
Calcium Chloride	0.1	-	0.35	-	-	-	-	-
Potassium Chloride	-	-	-	0.5	-	-	0.1	0.1
Water	to 100	to 100	to 100	to 100	to 100	to 100	to 100	to 100
<b>Exudate Release(g)</b>	<b>1.45</b>	<b>0.73</b>	<b>0.96</b>	<b>1.15</b>	<b>0.72</b>	<b>0.39</b>	<b>0.18</b>	<b>1.46</b>
<b>Force To Rupt.(N)</b>	<b>76</b>	<b>No Rupt.</b>	<b>14</b>	<b>24</b>	<b>133</b>	<b>150</b>	<b>N/A</b>	<b>52</b>
<b>% Compression</b>	<b>32</b>	<b>No Rupt.</b>	<b>36</b>	<b>41</b>	<b>39</b>	<b>50</b>	<b>N/A</b>	<b>77</b>

1. Kelgum™ is a 1:1 mixture of xanthan gum and locust bean gum supplied by Kelco, San Diego, CA, USA.

CLAIMS

1. A pre-formed, gel sheet device which is a patch or mask for delivering benefit agents to the skin, hair or nails, comprising from about 30% to about 99.5% of water and a mixture of at least two water-soluble polymeric gel forming agents, wherein the gel comprising the device has an exudate release of greater than 0.7 grams and less than 1.3 grams; a percentage compression at rupture of greater than 45% and less than 90%; and requires a force to rupture of greater than 30 N.
2. A pre-formed, gel sheet device according to Claim 1 having an exudate release of greater than 0.8 grams.
3. A pre-formed, gel sheet device according to any of Claims 1 or 2 having an exudate release of less than 1.2 grams.
4. A pre-formed, gel sheet device according to any of Claims 1 to 3 requiring a force to rupture of greater than 60N.
5. A pre-formed, gel sheet device according to any of Claims 1 to 4 requiring a force to rupture of greater than 80N.
6. A pre-formed, gel sheet device according to any of Claims 1 to 5 having a percentage compression at rupture of greater than 50%.
7. A pre-formed, sheet like device according to any of Claims 1 to 6 having a percentage compression at rupture of less than 80%.
8. A pre-formed, gel sheet device according to any of Claims 1 to 7 wherein the device comprises less than 30% of a mixture of water-soluble polymeric gel forming agents.
9. A pre-formed, gel sheet device according to any of Claims 1 to 8 wherein the mixture of water-soluble polymeric gel forming agents comprises at least one polysaccharide.
10. A pre-formed, gel sheet device according to any of Claims 1 to 9 wherein the mixture of water-soluble polymeric gel forming agents is a polysaccharide mixture.
11. A pre-formed, gel sheet device according to any of Claims 1 to 10 wherein the polysaccharide mixture comprises;
  - (i) at least one red seaweed polysaccharide, and;
  - (ii) at least one fermentation polysaccharide; glucomannan; galactomannan; and derivatives or mixtures thereof.

19. A pre-formed, gel sheet device according to any of Claims 1 to 17 which further comprises a benefit agent selected from anti-wrinkle and anti-skin atrophy actives, anti-acne actives, artificial tanning agents and accelerators, skin repair actives, skin barrier repair aids, skin lightening agents, skin sensates, skin soothing agents, lipids, sebum inhibitors, sebum stimulators, sunscreens agents, protease inhibitors, skin tightening agents, and desquamation enzyme enhancers, or mixtures thereof.
20. A pre-formed, gel sheet device according to any preceding Claim which further comprises from about 1% to about 45% of a humectant.
21. A pre-formed, gel sheet device according to any preceding Claim having a thickness of from about 0.5 mm to about 20 mm.
22. A cosmetic method of treatment comprising applying to the skin, hair or nails a pre-formed, gel sheet device according to any of Claims 1 to 17, 19, 20 or 21.
23. A pre-formed, gel sheet device according to any of Claims 1 to 21 in the form of a mask or patch having a size and shape adapted to conform to the nails or cuticles, the hair or scalp, a human face or part thereof, legs, arms, hands, feet or human torso.
24. A pre-formed, gel sheet device according to any of Claims 1 to 21, in a form selected from the group consisting of: handwear; footwear; and body wrap.

# INTERNATIONAL SEARCH REPORT

Internat'l Application No

PCT/US 00/18107

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	CHEMICAL ABSTRACTS, vol. 92, no. 16, 21 April 1980 (1980-04-21) Columbus, Ohio, US; abstract no. 135153, XP002133670 abstract	1-24
A	& JP 54 135229 A (DASUKIN FRANCHISE) 7 April 1978 (1978-04-07) ---	1-24
A	EP 0 139 913 A (DIAMALT AG) 8 May 1985 (1985-05-08) page 6, line 33 -page 8, line 23; claims 1-8,11 ---	1-24
A	EP 0 911 017 A (KAO) 28 April 1999 (1999-04-28) page 3, line 44 -page 4, line 24; claims 1-10 ---	1-24
A	DATABASE WPI Derwent Publications Ltd., London, GB; AN 1996-157000 XP002133671 & JP 08 040882 A (ICHIMARU PHARCOS), 13 February 1996 (1996-02-13) abstract -----	1-24

Form PCT/ISA/210 (continuation of second sheet) (July 1992)

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 00/18107

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
GB 2084871 A	21-04-1982	CH 650924 A DE 3135917 A FR 2489693 A JP 57080313 A SE 448203 B SE 8105134 A	30-08-1985 27-05-1982 12-03-1982 19-05-1982 02-02-1987 11-03-1982
JP 4122262 A	22-04-1992	NONE	
JP 54135229 A	20-10-1979	JP 1390682 C JP 61057027 B	23-07-1987 04-12-1986
EP 139913 A	08-05-1985	DE 3335593 A AT 24193 T AU 571008 B AU 3332484 A CA 1228277 A DE 3461648 D DK 465184 A ES 536340 D ES 8505698 A FI 843789 A,B, JP 1594852 C JP 2016949 B JP 60094487 A PT 79277 A,B US 4661475 A US 4826700 A ZA 8407492 A	11-04-1985 15-12-1986 31-03-1988 04-04-1985 20-10-1987 22-01-1987 31-03-1985 01-06-1985 01-10-1985 31-03-1985 27-12-1990 18-04-1990 27-05-1985 01-10-1984 28-04-1987 02-05-1989 29-05-1985
EP 911017 A	28-04-1999	CN 1217911 A JP 2985083 B JP 11209262 A	02-06-1999 29-11-1999 03-08-1999
JP 8040882 A	13-02-1996	NONE	

Form PCT/ISA/210 (patent family annex) (July 1992)